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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,534	10/24/2003	Bernhard Wolf	10051-4U1	9885

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EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,534

Applicant(s)

WOLF ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/24/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/585,146, now U.S. Patent No. 6,656,678, filed on June 1, 2000. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

Although the specification does state in the first sentence that the instant application claims priority to parent Application No. 09/585,146, the specification also indicates that the instant application is a divisional of the parent. The claims in the instant application were not present in the parent application as filed. Thus, the instant application appears to be a continuation of the parent, not a divisional. Applicants may wish to correct the priority information accordingly.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, i.a., the term "bio-components that carry away surface material" (claim 1) is not adequately described. Although the genus of bio-components that carry away surface material is discussed in the specification, there is no evidence that any representative species of such a large and varied genus was in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. The specification does not disclose any representative species of any of the recited class of possible bio-components, with or without identifying characteristics. Therefore, claim 1, as written, fail to satisfy the written description requirement.

Similarly, with respect to claim 8, no description of the genus of bio-components that are "material-selective specialized for carrying away one or more materials" is provided in the specification.

With respect to claims 1, 9 and 11, no description of an "osmotic protecting medium" is provided in the specification.

Claim 2 recites a "separation product," but no description of a separation product appears in the specification.

Claims 2, 5, and 7 recite the genus of bio-components that are "adherently attached" to the surface of an object, but no description of the functional limitation of adherent attachment (e.g., in contrast to other forms of attachment) is provided in the specification.

Claim 5 also recites the genus of bio-components that "form a surface structure." No description of such bio-components or such surface structures is provided in the specification.

Claim 12 recites the genus of "surface structure-selective bio-components" that attach to a surface layer having a certain structure. No description of this genus of bio-components is provided in the specification, nor is it described how they attach in a structure-specific manner to the surface.

Thus, as discussed above, although these genera of bio-components, osmotic protecting medium and separation product are discussed in the specification, there is no evidence that any representative species of any of these large and varied genera was in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species

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within the genus must be disclosed. The specification does not disclose any representative species of any of the recited classes of bio-components, osmotic protective media or separation products, with or without identifying characteristics. Therefore, claims 1-12, as written, fail to satisfy the written description requirement.

Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims read on "bio-components that carry away surface material" (claim 1), bio-components that are "material-selective specialized for carrying away one or more materials" (claim 8), bio-components that are "adherently attached" (claims 2, 5 and 7), bio-components that "form a surface structure" (claim 5), and bio-components that are "surface-structure selective" (claim 12). Thus, the claims read on any biological molecule or entity that, respectively, carries away surface material; is specialized in any way to carry away material from a the surface of selected material; is attached so that it adheres to any surface; forms any sort of structure on any surface; or has any sort of selective property for any surface structure.

The instant claims also read on an "osmotic protective medium" (claims 1, 9 and 11) and on a "separation product" (claim 2). Thus, the claims read on any osmotic

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protecting medium used with any bio-component and any separation product produced by any bio-component.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to any biological molecule or entity that, respectively, carries away surface material; is specialized in any way to carry away material from a the surface of selected material; is attached so that it adheres to any surface; forms any sort of structure on any surface; or has any sort of selective property for any surface structure. The specification is also not enabling for any osmotic protecting medium used with any bio-component and any separation product produced by any bio-component.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in

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determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Because there is no description of "bio-components that carry away surface material;" bio-components specialized in any way to carry away material from a the surface of selected material; bio-components that are attached so that they adhere to any surface; bio-components that form any sort of structure on any surface; or bio-components that have any sort of selective property for any surface structure, one of skill in the art would have to use undue experimentation to figure out what "bio-component" to use to perform each of these functions. The quantity of experimentation would be immense since the number of "bio-components" is unlimited, the amount of guidance is zero, the predictability is zero because the behavior of undefined materials is inherently unpredictable, the specification is devoid of working examples, the state of the art is that no "bio-components that carry away surface material" are known, the level of skill in this art is high, that of a highly trained and experienced research biologist, the nature of the invention cannot be adequately determined from the specification, and the breadth of the claims is vast.

Additionally, because there is no description of "osmotic protective medium" or "separation product," one of skill in the art would have to use undue experimentation to figure out what "osmotic protective medium" to use in the claimed invention and what

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“separation product” to use in the claimed invention so that the separation product may be separated by a bio-component that carries away surface material. The quantity of experimentation would be immense since the number of osmotic protective media is unlimited, while the number of separation products cannot be determined at all, the amount of guidance is zero, the predictability is zero because the behavior of undefined materials is inherently unpredictable, the specification is devoid of working examples, the state of the art is that no “bio-components that carry away surface material” are known, the level of skill in this art is high, that of a highly trained and experienced research biologist, the nature of the invention cannot be adequately determined from the specification, and the breadth of the claims is vast.

Accordingly, claims 1-12 fail to satisfy the enablement requirement.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,605,836). Chen discloses a process for structuring the surface layer of an object (a fluid conveying system of a food processing plant, medical device, airplane fuel tank or pipeline filter, or a wastewater discharge line of a heat exchanger in a nuclear power plant), in which the surface of the object is contacted with a bio-

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component in a nutrient medium (a biofilm, which comprises a microorganism in a protective film). The bio-component structures the surface of the object by removing pieces of it and causing pitting. Pieces of the object's surface are removed when the biofilm is rinsed with a biocidal solution (see col. 1, lines 7-45). Thus, a holding of anticipation is required.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dickerson (US 5,433,854). Dickerson discloses a process for structuring the surface layer of an object (the interior surfaces of a concrete waste water lift station), in which the surface of the object is contacted with a bio-component in a nutrient medium (a bacterial biofilm that is nourished by gases above the water). The bio-component structures the surface of the object by removing calcium, silica and other elements from the concrete. The nutrient medium is removed when the biofilm is rinsed with a mixture of air and ozone that is passed over the biofilm at a suitable velocity (see col. 3, lines 19-41; col. 4, line 63, to col. 5, line 4; and col. 5, lines 21-350). Thus, a holding of anticipation is required.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kakizawa et al. (US 6,143,705). Kakizawa discloses a process for structuring the surface layer of an object (semi-conductor substrate), in which the surface of the object is contacted with a bio-component, an acid that is naturally present in cells, such as acetic acid, lactic acid, citric acid, aspartic acid or glutamic acid, and an osmotic protective medium, such as solution of ammonium chloride. The bio-component binds surface materials such as iron, aluminum and copper ions. When the bio-component

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and osmotic protective solutions are rinsed off, the surface materials are removed (see col. 2, line 62, to col. 4, line 9; col. 5, lines 53-61; and col. 6, lines 38-51). Thus, a holding of anticipation is required.

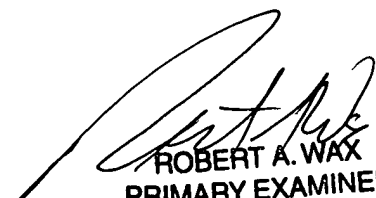
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
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ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653

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